Model_Informed_Consent

The tools and guidance documents on this website are provided to assist the caBIG® community in facilitating data sharing activities. They are not legal advice, nor does their distribution or use create an attorney-client relationship. Users should consult with their own legal advisers to assure compliance with all applicable federal and state laws and institutional policies.

Contents

- 1 Draft Model Informed Consent Form
- 2 caBIG® Plug-In
- <u>3 Consent and Authorization Elements Decision</u> Support Tool
- <u>4 Research Subject Discontinuation Documentation</u>
- <u>5 Summary of Standardization and Simplification</u> Initiatives
- 6 Open Consent Protocol
- 7 Relevant Bibliography

Draft Model Informed Consent Form

DSIC members have developed this combined informed consent and HIPAA authorization template to facilitate specimen and data collection and sharing for research. The document is a living document and will be further developed and revised over time. The posting of this document is not intended as an endorsement by any agency or individual but instead is a tool that can be adopted or adapted by researchers and research institutions at their discretion.

Please comment on the current version on our forums.

- DSIC Draft Informed Consent v 1.0
- DSIC Draft Informed Consent v 2.0
- DSIC Draft Informed Consent v 2.1 Current Version

caBIG® Plug-In

Researchers who would like to use their own or their institutions' standard templates, but include language to facilitate data sharing via caGRID and similar initiatives, might consider using language such as the following:

• caBIG® Plugin Language v 1.0 Current Version

Contents 1

Consent and Authorization Elements Decision Support Tool

This decision support tool is intended to be used in conjunction with the <u>Data Sharing and Security</u> <u>Framework</u> and <u>Data Sharing and Security Framework Decision Support Tool</u>. If you have questions or comments about this tool, please let us know in our <u>forums</u>.

• Consent and Authorization Elements v 1.0 Current Version

Link to Additional Decision Support Tools

Research Subject Discontinuation Documentation

These draft tools are intended to be used when a research subject is not continuing to take part in all or part of the research going forward. This discontinuation may result from an investigator or research subject decision. The worksheet is designed for use by the study team to document the discontinuation. The form is designed to be used when documentation of the subject withdrawal with the signature of the subject is requested per local policies.

- Subject Discontinuation Worksheet
- Subject Discontinuation Form

Summary of Standardization and Simplification Initiatives

Other model forms and toolkits have been publicized or are in development by other NIH and NCI components and by other government agencies, public foundations, and private entities. Descriptions of some recent informed consent simplification and standardization projects are provided here:

• Informed Consent Simplification Projects

Open Consent Protocol

A working draft "white paper" was written to evaluate several informed consent protocols for use in ongoing and future Molecular and Genomic Imaging Center (MGIC) research. Per the authors, the document is a working draft because it was not intended for formal publication. It has been made available to help foster discussion about the addressed issues.

• Draft? ?White Paper? on Informed Consent Protocols

Relevant Bibliography

Citations for articles of interest related to informed consent are provided here:

Beskow LM, Dean E. Informed consent for biorepositories: assessing prospective participants' understanding and opinions. Cancer Epidemiol Biomarkers Prev. 2008 Jun;17(6):1440-51.

Chen DT, Rosenstein DL, Muthappan P, Hilsenbeck SG, Miller FG, Emanuel EJ, Wendler D. Research with stored biological samples: what do research participants want? Arch Intern Med. 2005 Mar 28;165(6):652-5.

Pentz RD, Billot L, Wendler D. Research on stored biological samples: views of African American and White American cancer patients. Am J Med Genet A. 2006 Apr 1;140(7):733-9.

Relevant Bibliography